

REMARKS

Claims 12-97 and 99-136 are pending in the application and stand rejected. With this amendment, independent Claims 40, 84, 111, and 128 are amended. Dependent Claim 91 is amended to correct a typographical error. Upon entry of the amendments, Claims 40-53, 84-97, 99-101, 111-118, and 128-136 remain pending.

Product claims are cancelled, without prejudice, to expedite prosecution. The method Claims 40, 84, 11, and 128 are amended to recite the compression deformable temperature is below the melting point of the UHMWPE.

Support for the amendments is found in the specification as originally filed. Applicants respectfully request entry of the amendments.

OBJECTION TO THE APPLICATION

The application is objected to as lacking the written consent of all assignees. In response, Applicants offer a proper assent of the Assignee in compliance with 37 C.F.R. § 1.172 and 3.73. Applicants respectfully request the objection be withdrawn.

OATH/DECLARATION

The claims are rejected as being based on a defective reissue application declaration under 35 U.S.C. § 251. The reissue declaration filed with the application is said to be defective because it does not identify the foreign application in which priority is claimed. The reissue oath/declaration is said to be defective for the further reason that it fails to identify at least one error relied upon for the reissue application.

Applicants are obtaining a new reissue oath/declaration that overcomes the above listed objections. It will be provided prior to allowance of the present divisional application.

REJECTION UNDER 35 U.S.C. § 251

The claims are rejected under 35 U.S.C. § 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the reissue is based, U.S. Patent No. 6,168,626. Applicants respectfully submit the claims are not barred by the recapture rule because the broader aspects of the reissued claims do not relate to subject matter surrendered during prosecution. Applicants submit that the public is not prejudiced or surprised by the scope of the reissue claims, and the claims are not disfavored by the equitable nature of the recapture rule. Accordingly, Applicants respectfully traverse the rejection and request reconsideration.

A reissue is available whenever any patent is, through error and without deceptive intention, deemed wholly or partly inoperative or invalid by reason of the patentee claiming more or less than he had a right to claim in the patent. 35 U.S.C. § 251. A reissue patent can be granted enlarging the scope of the claims of the original patent if it is filed within two years from grant from the original. *Id.* Furthermore, of particular relevance to the present case, the statute relevant to divisional applications is applicable to reissue applications. *Id.* It provides that when two or more “independent and distinct”¹ inventions are claimed in one (reissue) application, the director may require restriction to one of the inventions. 35 U.S.C. §121.

The recapture rule is said to prevent a patentee from gaining, through reissue, the subject matter that he surrendered in an effort to obtain allowance of the original claims. Recapture is analyzed by a three step process. The first step is to determine whether and in what aspect the claims are broader than the (original) patent claims. The second is to determine whether the

¹ This statutory phrase is interpreted and applied by the Patent Office as though it read “ independent or otherwise distinct”” *See* MPEP §802.01.

broader aspects relate to surrendered subject matter. If the first two determinations are positive, then recapture bars the claims unless it is determined in a third step that the reissued claims are materially narrowed in other aspects to avoid the recapture rule. *Pannu v. Storz Instruments, Inc.* 258 F.3d 1366, 59 USPQ 2d 1597 (Fed. Cir. 2001); MPEP 1412.02.

Applicants submit that the present claims are not barred by the *Pannu* recapture rule for two basic reasons.

- First, the present claims are directed to a different invention than that prosecuted in the issued parent patent.
- Second, even if the present claims were improperly viewed as being the same invention as those issued in the '626 Patent, they are materially narrowed in other aspects so as to avoid recapture.

Reissue claims are distinct from the original claims of the issued US 6,168,626 parent patent.

The current reissue claims are drawn to an invention that is independent and distinct from that of the original claims. In the broadening reissue application, U.S. Application Serial No. 10/141,374, filed May 8, 2002, the Office required restriction between the current claims and the un-amended claims of the issued '626 Patent. In that restriction requirement, Claims 1-11 were the original claims (i.e. the claims to the invention of issued U.S. Patent No. 6,168,626), and were classified as Invention I. Those claims have since been examined, and their patentability confirmed. Other claims were classified in eleven total distinct and independent inventions.

Broadening aspects of the claims are not related to surrendered subject matter

Reissue claims to an invention that is independent and distinct from the issued patent claims may be broader than the claims of the issued patent, if presented within two years of the issuance of the patent. Whether such claims are broader or more narrow, they are inherently “new” claims, having never before been examined or considered. Applicants are entitled to file such independent and distinct claims, as long as the application otherwise provides support for the new claims.

Although the public is entitled to rely on subject matter surrendered during prosecution to establish its own ability to practice the claimed invention, such reliance does not reasonably extend to independent and distinct inventions not claimed, but not yet barred by the passage of two years from issue of the original claims. As noted above, the patent statute permits distinct inventions to be claimed in a reissue application filed within two years of the original claims. The public reading the original claims and the prosecution leading to their allowance would not consider that subject matter allegedly surrendered in the original claims could not be covered by later filed claims to an independent and distinct invention. In light of the statutory provisions, such consideration would not be reasonable.

Applicants’ remarks and amendments in pursuit of the original claims of the ‘626 Patent thus are not relevant to the scope of claims to a patentably distinct invention in a reissue divisional case like the current one. Any difference in scope between the original and the current claims is not ascribable to surrendered subject matter. Instead, the differences reflect the fact that the current claims are indeed “independent and distinct.” Because they are drawn to a distinct invention, the reissue claims are separately patentable over the prior art, for reasons that

may be different.² Because the inventions are distinct, it is to be expected that a search for such a distinct invention would turn up different art and/or that the art found in the search may be applied in a different way to the subject matter of the claims. It thus follows that arguments made for the patentability of a first set of distinct claims do not determine the scope of claims to a second distinct invention, since art is necessarily applied differently to the two inventions.

Therefore, any broadening aspects present in the distinct reissue claims will not be related to surrendered subject matter in the original claims. Because they are distinct from the original claims, their scope is not related to, and does not reflect, subject matter allegedly given up by amendment or argument during prosecution of the original claims. Rather, broadening aspects relative to the original claims are due solely to the fact that the reissue claims are drawn to an “independent and distinct” invention.

Thus, the subject matter of the present application is not the same subject matter of the original ‘626 Patent. Analysis for recapture is thus inapposite under the three prong analysis adopted by the Court of Appeals for the Federal Circuit in *Pannu*. Applicants respectfully request that the rejection of the claims as being an improper recapture be withdrawn.

Claims reciting heating below the melting point are materially narrowed in an aspect not completely unrelated to the rejection, and avoid the recapture rule

Further, even if it were to be held that broader aspects in the current reissue claims are related to surrendered subject matter, the amended claims -- reciting heating below the melting point -- do not fail the third prong of the *Pannu* recapture analysis. That is, in any event, the reissue claims are materially narrowed in other respects to avoid the recapture bar.

² Indeed, restriction among distinct inventions is only justified if, in addition, a search of the distinct inventions together would impose a “serious burden” if restriction is not required. MPEP § 808.

In *In re Clement*, 45 USPQ2d 1161 (Fed. Circ. 1997), the Court elaborated on the determination whether reissued claims are materially narrowed to avoid the recapture rule. As pertinent here, condition 3a) of the analysis reads

“If the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim....”

Clement, 45 USPQ2d at 1165. The above statement of the rule necessarily implies that the recapture rule does not bar the claim if the reissue claim is narrower in an aspect that is not completely unrelated to the rejection. That is, to avoid the recapture rule, a narrowing aspect offered in a reissue claim must be somehow related to the rejection (and not “completely unrelated to the rejection”). This leads to the statement of the rule in a “permissive” form:

“If the reissue claim... [is] narrower in another aspect not completely unrelated to the rejection, the recapture rule does not bar the claim.”

The reissue claims are now discussed with these principles in mind.

Claims 43, 87, 114, and 131 contain a narrowing aspect that is not “completely unrelated” to a claim rejection made during prosecution of the parent ‘626 Patent. They recite that the compression deformable temperature is below the melting point of the UHMWPE of the article. This is a narrowing aspect with respect to the parent claims, which recite a compression deformable temperature without a limit. But the narrowing aspect is not completely unrelated to the claim rejection in the ‘626 Patent. Note that, as demonstrated below, had the recitation of a compression temperature below the melting point been presented by amendment during prosecution, the claims would have distinguished over the art applied in the prosecution of the ‘626 Patent. For this reason, the narrowing aspect is definitely related to the claim rejection, or at least is not “completely unrelated” to the rejection.

As a result, the claims escape the recapture rule according to the analysis of the *Pannu* case. The prosecution of the parent claims is now discussed in light of the argument.

Amendment B responded to rejection of the parent claims over U.S. Patent No. 5,030,487, *Rosenzweig*. In the *Rosenzweig* reference, UHMWPE is expanded after crosslinking to make a heat shrink material that returns to its original shape upon heating. Applicants respectfully submit that *Rosenzweig* did not suggest compression deforming a crosslinked UHMWPE as in the rejected claims. Thus, the claims were patentable over *Rosenzweig* even without amendment. Further, had the claims at that time been amended to recite that the compression deformation was carried out at a temperature below the melting point, the claims would have even further distinguished from the reference. For this reason, the recitation that compression deformation is carried out below the melting temperature is not completely unrelated to the claim rejection — it is related to the claim rejection in that it would have been sufficient to make the claim patentable.

In Amendment F, the claims were amended from “molded article” to a “molded block” in part to distinguish over U.S. Patent No. 3,886,056, *Kitamaru et al.*, which disclosed fibers, films, and sheets. But Applicants note that *Kitamaru* called for making the fibers, films, and sheets, by heating the UHMWPE above the melting point and applying pressure. The recitation of compression deformation at a temperature below the melting point would have distinguished the reference without the other amendments. Thus, the narrowing aspect of compression deformation below the melting temperature is not “completely unrelated” to the rejection.

Similarly, in Amendment G, the parent claims were amended to recite a block having dimensions of 5 to 10 mm to distinguish over *Kitamaru*. But, as in Amendment F, an amendment at that time to recite a compression deformation temperature below the melting point of the UHMWPE would have distinguished over the reference. For this reason, such a

narrowing amendment offered in the reissued claims is not “completely unrelated” to the rejection.

Finally, in Amendment H, Applicants argued that the claims (reciting keeping the “deformed state under pressure”) distinguished over *Kitamaru*. Applicants stated “[in the reference], the rolled sheet from the rolls is free of pressure and then solidified without application of pressure.” But Applicants also stated “that, in the *Kitamaru* reference, the polyethylene is heated above the melting point before it is compressed and cooled.” For this reason, an amendment at that time to recite that compression deformation is carried out below the melting point would have distinguished the reference. For this reason, the narrowing aspect of compression deformation below the melting point is not “completely unrelated” to the rejection.

For all of the reasons discussed above, Applicants respectfully submit that the reissue claims do not violate the recapture rule. Accordingly, Applicants respectfully request the rejection be withdrawn.

ART REJECTIONS

Claims 12-36, 38, 39, 54-62, 66-76, 79-83, 102-110, 119-125, and 127 are rejected as anticipated by U.S. Patent No. 5,414,049, Sun et al.. Cancellation of these claims has mooted the rejection. Applicant respectfully request the rejection be withdrawn.

Claims 21, 22, 37, 63, 64, and 77 are rejected as obvious over *Sun* in view of U.S Patent No. 5,037,928, Li et al. These claims have been cancelled, so Applicants request the rejection be withdrawn.

Claims 12-20, 23-36, 38-48, 51-53, 102-118, and 128-136 are rejected as anticipated by *Kitamaru*. Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

The amended Claims 40-53, 84-101, 111-118, and 128-136 recite at least one limitation not found in *Kitamaru*. For example, all the claims are amended to recite the compression deformable temperature to which the UHMWPE is heated before deformation is below the melting point of the UHMWPE. In contrast, *Kitamaru* recites melting the UHMWPE prior to deformation.

The amended claims are not obvious in view of *Kitamaru* because modifying *Kitamaru* to arrive at the subject matter of the amended claims would render *Kitamaru* unsuitable for its intended purpose. An object of *Kitamaru* is to provide a process for producing polyethylene having a highly raised melting point. Col. 1, lines 50-51. The inventors report this effect is achieved “when the cross-linked polymer is extended or stretched in molten state and then cooled for crystallization.” Col. 2, lines 18-20. This teaches away from modifying *Kitamaru* to provide for heating the UHMWPE below the melting temperature, as recited in the amended claims.

Claims 1-97 and 98-136 are rejected as obvious over *Kitamaru* as applied above, and further in view of U.S. Patent No. 5,030,402, *Zacharaides*. Applicants respectfully traverse the rejection as applied to the amended claims and request reconsideration.

The deficiencies of *Kitamaru* are discussed above. They are not overcome by any combination with *Zacharaides*, except with the impermissible use of hindsight based on Applicants’ own disclosure. As noted in the Office Action, *Kitamaru* does not teach heating below the melting temperature after the deformation step, and does not teach or suggest

processing the component to make an artificial joint. Combining with *Zacharaides* to obtain the claimed invention amounts to picking and choosing among teachings of the references.

Zacharaides provides a specific “solid state deformation process” involving particular orienting of a preform in a mold comprising a mold cavity and a perimeter zone. The UHMWPE of *Zacharaides* is not crosslinked; the product of the solid state deformation is not further processed to make a medical implant. It is not immediately clear why the person of skill in the art would combine the references by adding some aspects of *Zacharaides* to *Kitamaru* (such as the heat treatment below the melting point) but not others (direct molding to a final implant, use of a non-crosslinked UHMWPE). Instead, it appears a rejection based on their combination is based on using the current claims as a roadmap to piece together teachings from the prior art. There is in particular no or rationale motivation to combine *Zacharaides* with *Kitamaru* as suggested in the Office Action.

In addition, neither reference suggests further processing of a treated UHMWPE to make a material suitable as a medical implant, as recited in amended Claims 84 and 128. For all of these reasons, Applicants respectfully request that the rejection be withdrawn.

REJECTION UNDER 35 U.S.C. § 112

Claims 1-97 and 99-136 are rejected as indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as his invention. Applicants traverse the rejection as applied to the amended claims and request reconsideration.

The specification describes the process steps in both broad and specific embodiments. Based on the following discussion, the current claims in fact distinctly claim the subject matter considered to be the invention.

Irradiation

Irradiation is disclosed broadly and generically:

Every kind of high energy rays can be employed as the high energy ray to be irradiated, for example a radioactive ray such as .gamma.-ray or X-ray, an electron beam, a neutron ray and the like. Among them, .gamma.-ray is superior in views of availability of irradiation apparatus and excellent permeability to materials. This irradiation of the high energy ray is carried out to generate crosslinking points in the molecular chains of the UHMWPE and then to produce intermolecular crosslinkage. The density of crosslinking is preferably such a very small degree that the crystallization is not prevented with ensuring a large elastic-deformation, for example 0.1 to 10, particularly 1 to 2 crosslinking points per one molecular chain. Col. 3, lines 26-39

A preferable dose of irradiation (energy) is the dose to give the above-mentioned density of crosslinking and 0.01 to 5.0 MR, preferably 0.1 to 3 MR in case of radioactive rays. Col. 3, lines 62-65.

The underlined terms illustrate non-limiting and functional description of the invention. After describing the broad purpose of irradiation (“to generate crosslinking points”), the specification lists preferable doses. Applicants do not consider that their invention is limited to any particular numerical dosage range.

Compression deformation

The claims recite that the crosslinked block is subjected to pressure at a deformation temperature (Claims 111 and 128) or that the block is subject to pressure after a heating step that brings the block to a compression deformable temperature (Claims 40 and 84). These are the steps of compression-deformation as described for example in column 4 of the specification:

The compression-deformation can be carried out, however, at a temperature of even around the melting point, for example 100° to 130° C. lines 12-14.

The compression-deformation is carried out under a pressure of 30 to 200 kgf/cm², usually 50 to 100 kgf/cm², with heating at the above-mentioned temperature. Lines 17-18.

Applicants respectfully that the amended claims encompass the above description and recite subject matter considered as the invention.

Cooling and solidifying

The specification describes embodiments in which the deformed state is maintained while cooling, and also embodiments where the deformed state is released prior to solidification. Thus at column 3, the invention is described without regard to maintaining or not the deformed state:

As described above, the oriented UHMWPE molded article can be obtained by irradiating a high energy ray to raw UHMWPE and then heating up and compression-deforming the UHMWPE, followed by cooling and solidifying. Col. 3, lines 16-20.

Later, in column 4, the concept of “keeping the deformed state” is introduced:

Then, the UHMWPE molded article having the molecular orientation or crystal orientation obtained by the compression-deformation as described above is cooled and solidified while keeping the deformed state. Col. 4, lines 34-37.

Then an alternative to keeping the deformed state is described:

If the deformed state is set free before solidification, the stretched molecular chains are relaxed in stress to return to the original state because the compression-deformation is conducted in the molten state.³ Col. 4, lines 37-41.

Finally, yet another embodiment of cooling and solidifying is described:

Also, before the cooling, the compression-deformed UHMWPE molded article may be subjected to isothermal crystallization at around 100° to 130° C., preferably 110° to 120° C., for 1 to 20 hours, preferably 5 to 10 hours, with keeping the deformed state, and then cooled to room temperature, preferably to 40° C. and solidified. Col. 4, lines 57-62.

The latter passage states the UHMWPE is cooled to room temperature and solidified, but does not require that compression force be maintained during the cooling.

The above passages indicate that many different embodiments of cooling and solidifying are considered by the inventors as part of their invention. The independent claims reflect this by reciting the block or article is “subjected to isothermal treatment” or is “cooled” after the deformation pressure is applied.

³ The cited passage is followed by a statement that “the deformed state must not be set free until solidified.” While not dismissing its significance, Applicants submit that taken in context with the other cited passages, it does not rise to a disavowal. After all, the statement follows a clear description of an embodiment where the pressure is released before solidification.

Processing to an implant

The written description discloses various methods of processing UHMWPE to make artificial joints. The invention is drawn to UHMWPE molded articles suitable for artificial joints. Column 1, lines 7-9. Artificial joints include hips, knees, elbow, finger, shoulders, and the like. Column 1, lines 25-27. Artificial joints are made of the UHMWPE described in the specification. Column 2, lines 60-62. In addition to these, the specification at col. 5, lines 4-8 state:

The compression-deformed molded article which is obtained as described above can also be processed to a socket for artificial joints by cutting and can be molded by means of the compression-deformation mold with a die comprising a convex and concave portions. *emphasis added*.

The above amounts to a fairly generic description of “processing” a UHMWPE to form an artificial implant, a process captured in Claims 84 and 128.

For these reasons, Applicants respectfully submit the rejected claims comply with the requirements of 35 USC § 112. Accordingly, Applicants respectfully request the rejection be withdrawn.

DOUBLE PATENTING


The claims are provisionally rejected on the grounds of non-statutory obviousness-type double patenting over the claims of co-pending U.S. Application Serial No. 11/522,504. Applicants note that this is a provisional rejection at this time because the conflicting claims have not in fact been patented. Applicants believe no action is needed to make a fully responsive reply. For this reason, Applicants reserve the right to obviate the rejection in the future by filing a terminal disclaimer, once patentable subject matter is determined in the current case.

CONCLUSION

For the reasons discussed above, Applicants submit that claims are in an allowable condition and respectfully request a notice of allowance. The Examiner is encouraged to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

Dated: 20 November 2017

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